Approval Date: MOV 1 4 2005

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-376

SULFAMED-G Soluble Powder (sodium sulfadimethoxine)

For treatment of coccidiosis or various bacterial diseases in chickens, turkeys, and cattle

Sponsored by:

Cross Vetpharm Group Ltd.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number: ANADA 200-376

b. Sponsor: Cross Vetpharm Group Ltd.

Broomhill Road, Tallaght

Dublin 24, Ireland

Drug Labeler Code: 061623

US Agent: Linda M. Duple

Director, North American Regulatory Affairs

Bimeda, Inc.

A Division of Cross Vetpharm Group Ltd.

2836 Dolliver Park Ave.

Lehigh, IA 50557

c. Established Name: Sodium sulfadimethoxine

d. Proprietary Name: SULFAMED-G Soluble Powder

e. Dosage Form: Soluble powder

107 g (3.77 oz) pouch 535 g (18.87 oz) pouch

25 lb (11.34 kg) pail

g. How Dispensed: OTC

f. How Supplied:

h. Amount of Active Ingredients: 107 g (3.77 oz) pouch: each packet contains

3.34 oz (94.6 g) Sulfadimethoxine in the

form of the soluble sodium salt and

disodium edetate.

535 g (18.87 oz) pouch: each packet contains 16.8 oz (473 g) Sulfadimethoxine

in the form of the soluble sodium salt and

disodium edetate.

25 lb (11.34 kg) pail: 3 scoops contain 3.34 oz (94.6 g) Sulfadimethoxine in the form of

the soluble sodium salt and disodium

edetate.

i. Route of Administration:

Oral

j. Species/Class:

Broiler and replacement chickens, meatproducing turkeys, dairy calves, dairy heifers, and cattle

k. Recommended Dosage:

Chickens: 1.875 (0.05 percent) grams per gallon of drinking water in automatic proportioners for six days.

Turkeys: 0.938 (0.025 percent) grams per gallon of drinking water in automatic proportioners for six days.

Cattle: 25 mg/lb first day followed by 12.5 mg/lb/day for 4 four days or 1.18 to 2.36 (0.031 to 0.062 percent) grams per gallon. Administer 2.5 grams per 100 pounds of body weight for first day, then 1.25 grams per 100 pounds of body weight per day for the next 4 consecutive days.

1. Pharmacological Category:

Antimicrobial, anticoccidial

m. Indications:

For Broiler and Replacement Chickens Only: Use for the treatment of disease outbreaks of coccidiosis, fowl cholera, and infectious coryza.

For Meat-producing Turkeys Only: Use for the treatment of disease outbreaks of coccidiosis and fowl cholera.

For Dairy Calves, Dairy Heifers, and Beef Cattle: Use for the treatment of shipping fever complex, bacterial pneumonia, calf diphtheria, and foot rot.

n. Pioneer Product:

ALBON; sodium sulfadimethoxine; NADA 046-285; Pfizer, Inc.

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor shows that the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Cross Vetpharm Group Ltd. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product SULFAMED-G (sodium sulfadimethoxine) Soluble Powder. The generic product is administered as an oral solution, contains the same active ingredients in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product, ALBON (sodium sulfadimethoxine) Soluble Powder, the subject of Pfizer, Inc., NADA 046-285, was approved on June 17, 1992.

3. HUMAN SAFETY:

• Tolerances for Residues:

The tolerance established for the pioneer product applies to the generic product. A tolerance 0.01 ppm is established for sulfadimethoxine residues in milk and uncooked edible tissues of chickens, turkeys and cattle under 21 CFR 556.640.

Withdrawal Times:

Because a waiver of the *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product.

The withdrawal times are 5 days for chickens and turkeys, and 7 days for cattle.

• Regulatory Method for Residues:

The analytical method for determination of sulfadimethoxine in tissues uses a thin layer-densitometric procedure. This method is found in the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 15th edition, 1990. The method is available from the Center for Veterinary Medicine, 7500 Standish Pl., Rockville, MD 20855.

4. AGENCY CONCLUSIONS:

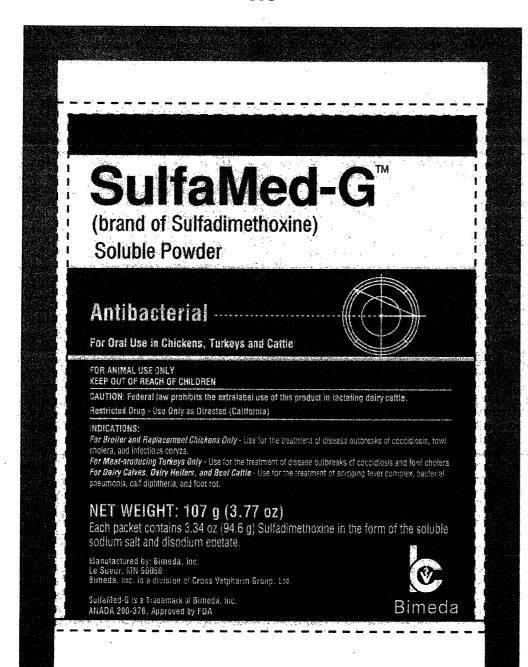
This ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that SULFAMED-G Soluble Powder, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile generic labeling and currently approved pioneer labeling are attached as follows:

Generic Labeling for ANADA 200-376: SULFAMED-G Soluble Powder 107 g (3.77 oz) pouch, front and back 107 g (3.77 oz) 25 packets label 535 g (18.87 oz) pouch, front and back 535 g (18.87 oz) 20 packets label 25 lb (11.34 kg) pail, front and back

Pioneer Labeling for NADA 046-285: ALBON Soluble Powder 107 g (3.77 oz) pouch, front and back





represents non-print area for 3/8" seal

yellow area represents pattern varnish 4.75" x 5.75"

4.5" X 5.5" image area front/back

5.5" X 7.5" pouch size

.5" X 1" eyemark

2" gap bottom of pouch

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Please review and approve: Copy, spelling, copy placement, size, shape, colors, unwind, and dieline. Authorized signature accepts responsibility for accuracy of all copy, color break and artwork. Lofton Label, Inc. is not liable for any discrepancies subsequently identified.

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Please Return To: Kim

LOFTON LABEL, INC. (651) 457-8118 • FAX (651) 457-3709

651) 457-8118 • FAX (651) 457-3709 6290 Claude Way E., Inver Grove Hts., MN 55076 JOB # 54040 DATE 9/8/05

PAGE _____ of _____

Size: 14.92" X 5.5" Cont. Dieline does not print.

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Rev. 10

Colors:

- 1 Black
- 2 248 Purple
- 3 877 Silver

SulfaMed-G[™] (brand of Sulfadimethoxine) Soluble Powder Antibacterial For Oral Use in Chickens, Turkeys and Cattle FOR ANIMAL USE ONLY KEEP OUT OF REACH OF CHILDREN CAUTION: Federal law prohibits the extralabel use of this product in lactating dairy cattle. Restricted Drug - Use Only as Directed (California) Net Contents: 25 Packets Each Containing: 107 g (3.77 oz) Each packet contains 3.34 oz (94.6 g) Sulfadimethoxine in the form of the soluble sodium salt and disodium edetate Manufactured by: Bimeda, Inc. Le Sueur, MN 56058 LOT: Birmeda, Ing. is a Division of Cross Velpharm Group, Ltd. EXP: Bimeda ANADA 200-376, Approved by FDA

Inside Yellow Dash is Not Varnished.

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JOB # 54036 DATE 9/8/05

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Rev. #8

Colors:

- 1 Black
- 2 PMS 248 Purple
- 3 PMS 877 Silver
- 4 Pattern Varnish

SulfaMed-G™

(brand of Sulfadimethoxine)
Soluble Powder

Antibacterial



For Oral Use in Chickens, Turkeys and Cattle

FOR ANIMAL USE DALY KEEP OUT OF REACH OF CHILDREN

CAUTION: Federal law prohibits the extralabel use of this product in lactating dairy callle. Restricted Drug - Use Only as Directed (California)

INDICATIONS

For Broiler and Replacement Chickens Only - Use for the treatment of disease outbreaks of occoldiosis, fewl cholera, and infectious corvza.

For Meat-producing Turkeys Only - Use for the treatment of disease outbreaks of coccidiosis and fowl cholera.

For Dairy Calves, Dairy Heifers, and Beef Cattle - Use for the treatment of shipping lever complex, bacterial pneumonia, call diphtheria, and foot rot.

NET WEIGHT: 535 g (18.87 oz)

Each packet contains 16.8 oz (473 g) Šulfadimethoxine in the form of the soluble sodium salt and disodium edetate.

Manufactured by: Bimeda, Inc. Le Sueur, MN 56058 Bimeda, Inc. is a division of Cross Vetpharm Group, Ltd.

SulfaMed-6 is a Trademark of Bimeda, Inc. ANADA 200-376, Approved by FDA



Bimeda

2.5" gap

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represents non-print area for 3/8" seal

yellow area represents pattern varnish 6.75" x 7.25

> 6.5" X 7" image area front/back

9.25" X 9.5" pouch size

> .5" X 1" eyemark

2.5" gap bottom of pouch

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6290 Claude Way E., Inver Grove Hts., MN 55076
JOB # 54038 DATE 9/8/05
PAGE 1 of 1
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Colors:

- 1 Black 2 248 Purple 3 877 Silver

SulfaMed-G™

(brand of Sulfadimethoxine) Soluble Powder

Manufactured by: Bimeda, Inc.

ANADA 200-376. Approved by FDA

Antibacterial ---For Oral Use in Chickens, Turkeys and Cattle KEEP OUT OF REACH OF CHILDREN Poduci No: 1SDM008 CAUTION: Federal law prohibits the extralabel use of this product in lactating dairy cattle. Restricted Drug - Use Only as Directed (California) Net Contents: 20 Packets Each Containing: 535 g (18.87 oz) Each packet contains 16.8 oz (473 g) Sulfadimethoxine in the form of the soluble sodium salt and disodium edetate.

Inside Yellow Dash is Not Varnished.

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LOFTON LABEL, INC. (651) 457-8118 • FAX (651) 457-3709 6290 Claude Way E, Inver Grove Hts., MN 55071 JOB # 54034 DATE 9/8/05

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Colors:

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SulfaMed-G

(brand of Sulfadimethoxine) Soluble Powder

Antibacterial

For Oral Use in Chickens, Turkeys and Cattle



FOR ANIMAL USE ONLY KEEP OUT OF REACH OF CHILDREN

CAUTION: Federal law prohibits the extralabel use of this product in lactating dairy cattle.

Restricted Drug - Use Only as Directed (California)

For Broiler and Replacement Chickens Only - Use for the treatment of disease outbreaks of coccidiosis, lowl choicra, and infectious conyza.

For Meat-graducing Turkeys Only - Use for the treatment of discase outbreaks of coccidiosis and fowl cholera.

For Dairy Calves, Dairy Heilers, and Beel Calife - Use for the treatment of shipping fever complex, pacterial pneumonia, caif diphtheria, and foot ret.

NET WEIGHT: 25 lb. (11.34 kg)

3 scoops contain 3.34 oz (94.6 g) Sulfadimethoxine in the form of the soluble sodium salt and disodium edetate.

Manufactured by: Bimeda, Inc. Le Sueur, MN 56058 Bimeda, Inc. is a division of Cross Vetpharm Group, Ltd.



SulfaMed-G is a Trademark of Bimeda, Inc. ANADA 200-376, Approved by FDA

Bimeda

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is Properticents.—To state stock solution, and controls of 15 secops to 2 gallons of water for chickens and to 4 gallons of orderer to feed at the of 1 if or of stock solution per gallon of water.

TREATMENT PERIOD - 6 consecutive days

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11.70	Stock Solution for Cattle*	1 gallon 1100 to body weight 1 gallon 1150 to body weight	
First Day Add	1 qued	10 gallons 7 gallons	
	2 queria	20 gelions 14 gallons	
100000000000000000000000000000000000000	1990	AUGUIS 20 gasts	*******
Next 4 Days Add	1 quet	20 galoris 14 galoris	*
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"Note: Makes a castle stock sockers by adulting 3 suppose of Suitable & Sakable Powder to 1 guillon of water.

"This design recommendation is based on a water concernation of 1 gallon per 100 to of body water per day, the expected water consumpting to the property of the expected water consumpting to the property of the expected water consumpting to the property of the expected water consumpting to the expected water consumption during cold mostles (winter) may drop permanent (30-10%). Accordingly, adjustments what he made in the district resource of individual cards, Suitablied-G Solates Powder, stock solution for cattle may be given as a directly.

which their scoops will medicate shi-0.01 by amount in the for theeler 500 to estimate on indicatemors dose.

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ESPUIE WARDINGS: CRICKERS AND TUBBLEYS - Windray'S days before staugries. Do not achimeter to discious over 15 week

(1)2 days) of age or to buttons over 24 seniors (100 days) of age.

CATTLE - Witnesse / days before statuting for days catese, dairy tellers and beet catifs only. A withdrawal period has not been explained for this product in pre-trainmant extrem. But but Use in Calves to be Propresed for Yeal.





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Product No: 1SDM007

EXP:

ALBON

(Brand of Sulfadimethoxine)

ANTIBACTERIAL SOLUBLE POWDER

Each packet contains 3.34 oz (94.6 g) sulfadimethoxine in the form of the soluble sodium salt and disodium edetate.

Restricted Drug (California)—Use Only as Directed

Not for Human Use

For Broiler and Replacement Chickens Only—Use for the treatment of disease outbreaks of coccidiosis, fowl cholera, and infectious coryza.

For Meat-producing Turkeys Only—Use for the treatment of disease outbreaks of coccidiosis and fowl cholera.

For Dairy Calves, Dairy Heifers, and Beef Cattle—Use for the treatment of shipping fever complex and bacterial pneumonia associated with Pasteurella spp. sensitive to sulfadimethoxine; and calf diphtheria and foot rot associated with Sphaerophorus necrophorus sensitive to sulfadimethoxine.



Net wt 3.77 oz (107 g)

NADA #046-285, Approved by FDA

SB SmithKline Beecham

Dosage and Administration

Species	Concentration	Use Directions
Chickens	0.05%	Contents of pecket to 50 gal of water
Turkeys	0.025%	Contents of packet to 100 gal of water

Automatic Proportioners—To make stock solution, add contents of 5 packets to 2 gal of water for chick and to 4 gal of water for turkeys. Set proportioner to feed at rate of 1 fl oz stock solution per gal of water for turkeys.

Dairy Calves, Dairy Heifers, and Beef Cattle

Dosage: 25 mg/lb first day followed by 12.5 mg/lb/day for 4 days.

Albon (sulfadimethoxine) in Water

£		Water Consumption							
• • •	Amount of Stock Solution for Cattle*	(Summer) 1 gal/100 lb body wt**	(Winter) 1 gal/150 lb body with						
First Day Add	1 qt	10 gal	7 gal						
	2 qt	20 gal	14 gal						
	1 gal	40 gal	28 gal						
Next 4 Days Add	t qt	20 gal	14 gai						
	2 qt	40 gal	28 gai						
	1 gal	80 gal	56 gai						

Note: Make a cattle stock solution by adding 1 packet of Albon Soluble Powder to 1 gal of water.

Twenty il oz of cattle stock solution will medicate 1 800-lb animal initially or 2 800-lb animals on maintenance do Contents of packet will medicate 8 600-lb animals initially or 12 800-lb animals on maintenance dose.

"This dosage recommendation is based on a water consumption of 1 gal per 100 lb of body weight per day, the pected water consumption during oold months (winter) may drop marked 30 40%). Accordingly, adjustments must be made in the dilution rates to compensate for this and insure proper lates.

For treatment of individual cattle, Albon (sulfadimethoxine) Soluble Powder stock solution for cattle given as a drench. Administer using same mg/lb dosage as outlined above. Treatment Period: 5 consecutive days

Courion: Chickens and Turkeys—If animals show no improvement within 5 days, discontinue treatment and revaluate diagnosis. Prepare a fresh stock solution daily. Handle the recommended dilutions (chickens 0.0 and turkeys 0.025%) as regular drinking water. Administer as sole source of drinking water and sulfonamide.

medication.

Chickens and turkeys that have survived fowl cholera outbreaks should not be kept for replacements or bro Cartie-During treatment period, make certain that animals maintain adequate water intake. If animals and improvement within 2 or 3 days, reevaluate diagnosis. Treatment should not be continued beyond 5 days.

Warning: Chickens and Turkeys—Withdraw 5 days before slaughter. Do not administer to chickens over 16 weeks (112 days) of age or to turkeys over 24 weeks (168 days) of age.

Cattle—Withdraw 7 days before staughter. For dairy calves, dairy heilers, and beef cattle only.

A withdrawal period has not been established for this product in pre-ruminating

Do Not Use in Calves to be Processed for Veal

Distributed by: SmithKline Beecham Animal Health Yest Chester, PA 19380, USA

942 704